

**REMARKS**

I. **Introductory Remarks**

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and following remarks.

It is acknowledged that the amendments are being presented after final rejection of the application; however, entry of the amendments is respectfully requested because Applicants believe that the amendments place the application in condition for allowance, without raising new issues or introducing new subject matter into the application.

Upon entry of the amendments, claims 21-25, 29 and 31 will remain pending in this application. Claims 21-23, 29 and 31 are being amended. No claims are being canceled or added.

Exemplary support for the claim amendments exists in the specification at page 5, lines 11-17; page 16, lines 14-17; page 16, line 22 – page 17, line 2; page 17, line 20 – page 18, line 4; page 20, lines 6-24; and original claims 12, 14, 22 and 24 .

II. **Claims 21-25, 29 and 31 Comply with 35 U.S.C. § 112, Second Paragraph**

Claims 21-25, 29 and 31 were variously rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention. Each basis for rejection is addressed below.

A. **Direct and Indirect Modulation**

Claims 24 and 31 remain rejected as allegedly being indefinite because the Office continues to question how antisense *nucleic acids* can modulate *Aurora protein* activity. According to the Examiner, “if applicant intends to claim a method of use of modulators of broader scope, he/she must amend claim 21 to refer to a method of use of modulators of both DNA and polypeptides.”

As explained in their previous response, Applicants maintain that antisense nucleic acids *indirectly* modulate Aurora protein activity by reducing the amount of Aurora protein in

cells. To advance prosecution, however, Applicants have amended claim 21 (from which claims 24 and 31 depend) to indicate that the administered substance may “modulate[] the kinase activity or expression of a full length AUR-1 or AUR-2 protein.” The amendment further clarifies that claim 21 encompasses (a) substances that affect Aurora protein expression, and (b) substances that directly interact with Aurora proteins to affect their kinase activity.

B. Sufficiency of Antecedent Basis

Claims 22-23 and 29 were rejected as being indefinite because the recitations “said disease” and “said at least one disease” allegedly lacked sufficient antecedent basis.

Although Applicants believe that the antecedent basis was clear and sufficient, the rejection is now moot. Amended claims 22-23 and 29 do not contain the subject recitations.

C. Protein v. Polypeptide

Claims 21-25, 29 and 31 were rejected as allegedly being indefinite because the reference to a “protein” in the claims contrasts with references to “polypeptides” throughout the specification.

Those skilled in the relevant art would understand that the terms “protein” and “polypeptide” are equivalent, as used in the rejected claims. Nonetheless, to advance prosecution, Applicants have amended claim 21 to recite the latter.

Accordingly, each of the rejections under 35 U.S.C. § 112, second paragraph, is now moot. Applicants therefore request withdrawal of the rejections.

III. Claims 21-22, 24-25, 29 and 31 Comply with the Enablement Requirement of 35 U.S.C. § 112, First Paragraph

Claims 21-22, 24-25, 29 and 31 remain rejected as allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. The Office acknowledged that the specification is “enabling for (i) method of treating colon and pancreatic cancer by administering to a patient in need of such treatment a substance that modulates the kinase activity of full-length AUR1 and (ii) a method [of] treating colon cancer by administering to a

patient in need of such treatment a substance that modulates the kinase activity of full-length AUR2.” However, The Office maintained that the specification does not sufficiently enable methods of treating cancers other than colon cancer and pancreatic cancer.

Applicants maintain, for reasons set forth in their previous response, that the specification enables the full scope of the rejected claims. The specification establishes a clear link between the Aurora polypeptides and each type of cancer recited by the claims. Additionally, the specification contains numerous working examples constituting strong evidence that one skilled in the art could practice the claimed methods without undue experimentation.

Strictly to advance prosecution of the application, however, Applicants have limited the pending claims to methods of (a) treating colon cancer by administering a substance that modulates the kinase activity or expression of a full length human AUR-1 or AUR-2 polypeptide, and (b) treating pancreatic cancer by administering a substance that modulates the kinase activity or expression of a full length human AUR-1 polypeptide. Thus, the scope of the amended claims conforms to the scope of subject matter that the Office already deemed enabled.

Because the specification fully enables amended claims 21-22, 24-25, 29 and 31, Applicants request withdrawal of the rejection.

IV. Claims 21-22, 24-25, 29 and 31 Comply with the  
Written Description Requirement of 35 U.S.C. § 112, First Paragraph

Claims 21-22, 24-25, 29 and 31 remain rejected as allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. More particularly, the Office stated that the genus of Aurora polypeptides is not adequately described because it embraces polypeptides “from any source and species.”

The amended claims clarify that the administered substance “modulates the kinase activity or expression of a full length human AUR-1 or AUR-2 polypeptide.

Accordingly, the rejection is moot and Applicants request its withdrawal.

V. Concluding Remarks

The application is now in condition for allowance, and Applicants request favorable reconsideration of it.

If the Examiner believes that a telephone interview will advance prosecution of the application, she is invited to contact the undersigned by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

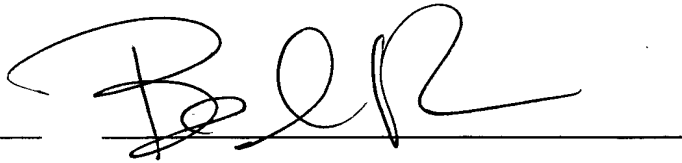
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